K003857

OCT 1 8 2001

510(k) Summary

Submitter: SterilMed, Inc.

Contact Person:
Patrick Fleischhacker
SterilMed, Inc.
11400 73rd Avenue North
Minneapolis, MN 55369
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Date Prepared: May 29, 2001

Trade Name: The SterilMed Intermittent Compression Sleeve, 400 Series

Classification Name and Number: Compressible Limb Sleeve
Class II, 21 CFR 870.5800

Product Code: JOW

Predicate Device(s): The SterilMed Intermittent Compression Sleeve, 400 Series is substantially equivalent to the Talley™ DVT-275 (K915638) and the WizAir™ Compression System (K002287). This conclusion is based upon the devices' similarities in intended use, device categorization, technological and performance characteristics, and materials.

Device Description: **Note:** the subject of this submission is the compression sleeve only. The pneumatic compressor (pump) is not part of this submission, as it is a separately cleared (K915638) device that is being distributed by SterilMed.

The SterilMed 400 Series consists of:

- A series of SterilMed Intermittent Compression Sleeves that are different shapes for different anatomical applications. They are designed to apply compression to patients' extremities while used in conjunction with a pump that provides air to the sleeves in an intermittent fashion.

The compression sleeves are comprised of two components:

- The outer garment that holds the bladder in the proper orientation on the limb; and
- The bladder, which inflates and applies compression to the appropriate areas of the limb.

Intended Use:	The SterilMed Intermittent Compression Sleeve, 400 Series used in conjunction with the Talley™ DVT-275 pump is indicated for any person that is at risk for deep vein thrombosis or could otherwise benefit from enhanced blood flow and circulation and/or a reduction in post operative pain and swelling.
Clinical Data:	No clinical data was submitted with this submission.
Non-Clinical Performance Testing:	Testing of the Intermittent Compression Sleeves included: burst testing which measured the burst pressure of the bladder; kink resistance testing which measured the compression sleeve's ability to function following kinking of the air delivery tubes; leakage testing which measured the capability of the device to withstand inflation pressure and hold pressure without leaking; cycle time testing which measured the cycle times and maintenance of pressures; and temperature distribution testing which measured the temperature on the patient contact side of the sleeve during normal use.
Conclusion:	Testing has demonstrated that the performance of the SterilMed Intermittent Compression Sleeve, 400 Series is substantially equivalent to the predicate devices and raise no new questions of safety or risk to the patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2001

Mr. Patrick Fleischhacker
VP Regulatory Affairs and Quality Assurance
SterilMed, Inc.
11400 73rd Avenue North
Minneapolis, MN 55369

Re: K003857
Trade/Device Name: SterilMed Intermittent Compression Sleeve, 400 Series
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: September 21, 2001
Received: September 24, 2001

Dear Mr. Fleischhacker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

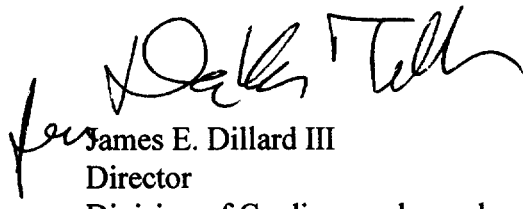
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Page K003857

Device Name: SterilMed Intermittent Compression Sleeve, 400 Series

Indications for Use: The SterilMed Intermittent Compression Sleeve, 400 Series used in conjunction with the Talley™ DVT-275 pump is indicated for any person that is at risk for deep vein thrombosis or could otherwise benefit from enhanced blood flow and circulation and/or a reduction in post operative pain and swelling.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003857

Prescription Use ✓
(Per 21 CFR 801.109)